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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,710	10/09/2001	Peggy-Jean P. Flanigan	55526US003	7863

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EXAMINER

CHEVALIER, ALICIA ANN

ART UNIT	PAPER NUMBER
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1772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/974,710

Applicant(s)

FLANIGAN ET AL.

Examiner

Alicia Chevalier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-17,19-22,26-53 and 55-60 is/are pending in the application.
- 4a) Of the above claim(s) 36-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-17,19-22,26-35,53 and 55-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

RESPONSE TO AMENDMENT

Request for Continued Examination

1. The Request for Continued Examination (RCE) under 37 CFR 1.53 (d) filed on October 18, 2006 is acceptable and a RCE has been established. An action on the RCE follows.
2. Claims 1, 3-8, 10-17, 19-22, 26-53 and 55-60 are pending in the application, claims 36-52 are withdrawn from consideration. Claims 2, 9, 18, 23-25, 54 and 61-67 have been cancelled.
3. Amendments to the claims, filed on October 18, 2006, have been entered in the above-identified application.

WITHDRAWN REJECTIONS

4. The 35 U.S.C. §102 rejections made of record in the office action mailed July 18, 2006, pages 2-7, paragraphs 6-8 has been withdrawn due to Applicant's amendment in the response filed October 18, 2006.
5. The 35 U.S.C. §103 rejections made of record in the office action mailed October 18, 2006, pages 7-11, paragraphs 10-14 has been withdrawn due to Applicant's amendment in the response filed October 18, 2006.

REJECTIONS

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

7. Claims 1, 3-8, 10-17, 19-22, 26-35, 53 and 55-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations “structured surface” and “non-structured surface” in claims 1, 22 and 53 are unclear which renders the claims vague and indefinite. In view of the specification it is unclear what is meant by “structured,” since Applicant does not define the term. The term “structured” refers to any type of structure which includes flat surfaces, since flat surfaces are a type of structure. The term “non-structured surface” is even more unclear since a non-structured surface would be a surface lacking any type of structure including a flat surface. For purposes of examination since these terms are very unclear as to the desired surface configuration, the terms are considered to just be terms for opposing sides of the adhesive.

Claim 1 recites the limitation "the adhesive layer" in line 4. There is insufficient antecedent basis for this limitation in the claim. Applicant only has antecedent basis for “at least one adhesive layer.”

The limitation “exposed adhesive surface” in claim 1 is unclear and renders the claim vague and indefinite. It is unclear whether this “adhesive surface” is part of the “at least one adhesive layer” or if Applicant is claiming another adhesive layer.

Claim 1 recites the limitation " exposed adhesive surface " in line 8. There is insufficient antecedent basis for this limitation in the claim. Applicant only has antecedent basis for “at least one adhesive layer.”

Claim 6 recites the limitation "the adhesive layer" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant only has antecedent basis for "at least one adhesive layer."

Claim 6 is unclear which renders it vague and indefinite. Claim 1 clearly states that the at least one adhesive layer has a first or second surface which is structured. Therefore, it is unclear how the at least one adhesive layer could be a "non-structured adhesive layer."

Claims 20 and 21 are unclear which renders it vague and indefinite. If the second major surface of the at least one adhesive layer further comprises a backing layer how can there be an exposed adhesive surface?

Claim Rejections - 35 USC § 102

8. Claims 1, 3, 4, 6-8, 11-13, 15, 17, 19-22, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (U.S. Patent No. 3,179,552).

Hauser discloses an article (*tape, title*) comprising at least one adhesive layer (*figure 2*) with a first major surface and a second major surface wherein at least one of the first and second major surface is a structured surface and a backing laminated (*film backing, figure 2*) to the structured surface of the adhesive layer wherein the exposed surface of the backing is unstructured (*figure 2*), wherein the article comprises discrete reservoirs or channels (*figure 2*) between the structured surface of the adhesive layer and the backing and wherein the article has a non-structured exposed adhesive surface that can be adhered to a target substrate (*figure 2*). The at least one adhesive comprises a tacky rubber-resin type pressure sensitive adhesive (*col. 1, lines 53-54*). The article further comprises at least one non-adhesive layer in contact with one of the

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first and second major surfaces (*figure 2*) and comprises a non-structured exposed surface (*figure 2*). The article comprises a plurality of channels (*figure 2*). The reservoirs/channels contain at least one non-deliverable solid substance (*yarns, col. 1, lines 51-52*). The backing is deemed to be a laminate (*figure 2*).

Hauser discloses a tape comprising at least one pressure sensitive adhesive layer comprising a first major surface and a second major surface, wherein the first major surface is a structured surface and the second major surface is a non-structured surface and a non-adhesive flexible backing laminated to the first major surface, wherein the tape comprises discrete reservoirs/channels between the structured surface of the adhesive layer and the backing (*figure 2 and col. 1, lines 42-46*). The tape is deemed to have a peel strength of at least 21-42 oz/0.5 inch for a thickness of 0.0003 to 0.007 inches, since Hauser also discloses a pressure sensitive adhesive layer and a backing layer.

9. Claims 1, 3, 4-8, 11-17, 19-22 and 26-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hidaka et al. (U.S. Patent No. 4,801,458).

Hidaka discloses an article comprising at least one adhesive layer (*figure*) with a first major surface and a second major surface wherein at least one of the first and second major surface is a structured surface and a backing laminated (*figure, reference #1 and #2*) to the structured surface of the adhesive layer wherein the exposed surface of the backing is unstructured (*after release sheet 5 is removed, figure and col. 3, lines 1-2*), wherein the article comprises discrete reservoirs or channels (*figure and col. 2, lines 67 through col. 3, line 2*) between the structured surface of the adhesive layer and the backing and wherein the article has a

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non-structured exposed adhesive surface that can be adhered to a target substrate (*figure*). The at least one adhesive comprises a rubber-resin type pressure sensitive adhesive etc. (*col. 6, line 67 through col. 7, line 22*). The thickness of the article is about 2-500 micrometers (*col. 7, lines 27-29 and col. 9, lines 25-27*). The article further comprises at least one non-adhesive layer in contact with one of the first and second major surfaces (*figure*) and comprises a non-structured exposed surface (*figure*). The reservoirs/channels contain at least one non-deliverable and deliverable substance such as drugs (*hollow fibers containing medicine, col. 1, lines 11-13 and col. 4 line 28 through col. 6, line 43*). The backing is deemed to be a laminate (*figure*). The second major surface further comprises a backing layer (*release sheet, figure and col. 3, lines 1-2*).

Hidaka discloses a tape comprising at least one pressure sensitive adhesive layer comprising a first major surface and a second major surface, wherein the first major surface is a structured surface and the second major surface is a non-structured surface and a non-adhesive flexible backing laminated to the first major surface, wherein the tape comprises discrete reservoirs/channels between the structured surface of the adhesive layer and the backing (*figure and col. 6, line 67 through col. 7, line 22*). The tape is deemed to have a peel strength of at least 21-42 oz/0.5 inch for a thickness of 0.0003 to 0.007 inches, since Hidaka also discloses a pressure sensitive adhesive layer and a backing layer.

10. Claims 53 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamilton et al. (U.S. Patent No. 5,662,758).

Hamilton discloses an article comprising at least one first layer with a first major surface and a second major surface, wherein at least one of the first and second major surface is a structured surface, and a cap layer laminated to a structure surface of the first layer, wherein the cap layer comprises an adhesive and wherein the cap layer is non-structured on both surfaces and wherein the artic has a non-structured exposed surface that can be adhered to a target substrate (*figure 10 and figure 4*). The first layer comprises a polymeric film (*col. 6, line 1*).

Claim Rejections - 35 USC § 103

11. Claims 11 and 56-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al. (U.S. Patent No. 4,801,458).

Hidaka is relied upon as described above.

Hidaka fails to disclose that the reservoir has a void volume of less than 100 microliters.

The exact void volume of the reservoir is deemed to be a result effective variable with regard to the amount of medication needed. It would require routine experimentation to determine the optimum value of a result effective variable, such as void volume, in the absence of a showing of criticality in the claimed volume. *In re Boesch*, 205 USPQ 215 (CCPA 1980), *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). One of ordinary skill in the art would have been motivated to use a small void volume in order not to over medicate a patient.

ANSWERS TO APPLICANT'S ARGUMENTS

12. Applicant's arguments in the response filed October 18, 2006 regarding the previous rejections of record have been considered but are moot due to the new grounds of rejection.

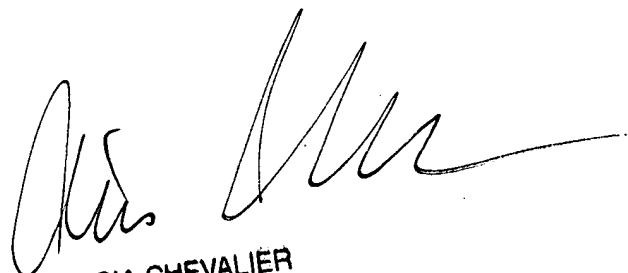
Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Chevalier whose telephone number is (571) 272-1490. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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1/5/07



**ALICIA CHEVALIER
PRIMARY EXAMINER**